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Derivation of Human Health-Based Ambient Water Quality Criteria: A Consideration of Conservatism and Protectiveness Goals

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ABSTRACT

Under the terms of the Clean Water Act, criteria for the protection of human health (Human Health Ambient Water Quality Criteria [HHWQC]) are traditionally derived using US Environmental Protection Agency (USEPA) recommended equations that include parameters for exposure assessment. To derive “adequately protective” HHWQC, USEPA proposes the use of default values for these parameters that are a combination of medians, means, and percentile estimates targeting the high end (90th percentile) of the general population. However, in practice, in nearly all cases, USEPA's recommended default assumptions represent upper percentiles. This article considers the adequacy of the exposure assessment component of USEPA recommended equations to yield criteria that are consistent with corresponding health protection targets established in USEPA recommendations or state policies, and concludes that conservative selections for exposure parameters can result in criteria that are substantially more protective than the health protection goals for HHWQC recommended by USEPA, due in large part to the compounding effect that occurs when multiple conservative factors are combined. This situation may be mitigated by thoughtful selection of exposure parameter values when using a deterministic approach, or by using a probabilistic approach based on data distributions for many of these parameters. *Integr Environ Assess Manag* 2014;9999: XX--XX. © 2014 SETAC

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INTRODUCTION

Section 304(a)(1) of the Clean Water Act (CWA) requires the US Environmental Protection Agency (USEPA) to develop and publish recommended numeric ambient water quality criteria (AWQC) for limiting the impact of pollutants on human health and aquatic life. These recommended human health-based ambient water quality criteria (HHWQC) are intended to provide guidance for states and tribes to use in adopting their own water quality standards and are meant to “minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposures to substances through the ingestion of drinking water and consumption of fish obtained from surface waters” (USEPA 2000a).

During the course of recent regular reviews of water quality criteria, a number of states have received stakeholder opinions, via public meetings or during open comment periods, suggesting that certain water quality criteria may be insufficiently protective of human health. For the most part, such assertions have been related to rates of fish consumption, which is only one of several parameters of the exposure assessment component in criteria derivation. However, consideration has seldom been given to the adequacy of the entire exposure assessment component of the methodology to yield criteria that are consistent with corresponding health protection targets established in USEPA recommendations or state policies. This article discusses the level of protectiveness mandated by the Clean Water Act, USEPA’s interpretation of that mandate, and the approaches USEPA recommends to achieve protection targets. An attempt is made to assess consistency between USEPA’s recommended approaches and health protection targets using a quantitative assessment of the level of conservatism embodied in the default exposure parameters used in USEPA’s HHWQC derivation methodology. Finally, alternative approaches that derive HHWQC that more directly correspond to specified levels of protectiveness are discussed.

USEPA APPROACH TO ACHIEVING CWA-MANDATED PROTECTIVENESS

The CWA specifies, in a broad sense, the level of protectiveness that should be embodied in the HHWQC. It includes language such as “protect the public health and welfare,” “protect public health… from any reasonably anticipated adverse effects of each pollutant,” and “[not] pose an unacceptable risk to human health.” In its HHWQC methodology document, USEPA notes that HHWQC are usually derived to protect the majority of the general population from chronic adverse health effects and that it

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considers the target protection goal to be satisfied if the population as a whole will be adequately protected by the human health criteria when the criteria are met in ambient water (USEPA 2000a). USEPA (2004) further clarifies its overall protectiveness goals by stating that "EPA typically cannot protect every individual but rather attempts to protect individuals who represent high-end exposures (typically around the 90th percentile and above) or those who have some underlying biological sensitivity; in doing so, EPA protects the rest of the population as well."

HHWQC are traditionally derived using USEPA recommended equations (Eqns. 1, 2, and 3) that include explicit parameters for allowable risk and toxicity, and several parameters that determine exposure, including body weight, drinking water intake, fish intake, bioaccumulation, and a relative source contribution factor for noncarcinogens. Inherent to HHWQC are other assumptions not shown in the equations, referred to as implicit assumptions in this article, including duration of exposure, cooking loss, relative absorption, and the concentration of a chemical in water. The exposure assessment portion of the analyses, "BW/(DI + (ΣFIi × BAFi)," which is the primary focus of this article, is the same in all 3 equations.

For noncarcinogenic effects

$$\mathrm{RfD} \times \mathrm{RSC} \times (\mathrm{BW}/(\mathrm{DI} + (\sum \mathrm{FIi} \times \mathrm{BAFi}))), \qquad (1)$$

for carcinogenic effects (nonlinear)

$$(\mathrm{POD}/\mathrm{UF}) \times \mathrm{RSC} \times (\mathrm{BW}/(\mathrm{DI} + (\sum \mathrm{FIi} \times \mathrm{BAFi}))), \text{ and} \qquad (2)$$

for carcinogenic effects (linear)

$$\mathrm{RSD} \times (\mathrm{BW}/(\mathrm{DI} + (\sum \mathrm{FIi} \times \mathrm{BAFi}))), \qquad (3)$$

where RfD = reference dose for noncancer effect (mg/kg-d), RSC = relative source contribution factor for sources of exposure not accounted for by DI or FIi, POD = point of departure for carcinogenic effects based on a nonlinear low-dose extrapolation, UF = uncertainty factor for carcinogenic effects based on a nonlinear low-dose extrapolation, RSD = risk-specific dose for carcinogenic effects based on a linear low-dose extrapolation, BW = human body weight (kg), DI = drinking water intake (L/day), FIi = fish intake at trophic level (TL) i (i = 2, 3, and 4), and BAFi = bioaccumulation factor at trophic level i, lipid normalized (L/kg).

USEPA (2000a) states that to derive HHWQC that are "adequately protective," it selects default parameter values that are "a combination of median values, mean values, and percentile estimates [that target] the high end of the general population."

CONSERVATISM IN INDIVIDUAL EXPOSUE ASSESSMENT PARAMETERS

Although USEPA recommends the use of parameter values that are "a combination of median values, mean values, and percentile estimates [that target] the high end of the general population" (USEPA 2000a), examination of the default values recommended by USEPA reveals that in fact, the selection of the recommended explicit exposure parameters and the assumptions that are implicit in the criteria derivation represent values taken from the upper end of the range of available data in nearly all cases. We have compared, to the extent possible, HHWQC calculated using currently recommended default exposure parameter values and those calculated using mean or median values, or, in the case of BW, more recent data.

Relative source contribution

The relative source contribution (RSC), which is used in the derivation of HHWQC for substances with noncarcinogenic effects, determines what portion of the RfD will be allocated to the consumption of water and fish from regulated waterbodies (USEPA 2000a). USEPA (2000a) provides a decision tree methodology for calculating chemical- or site-specific RSCs, notes that the information required to calculate those RSCs "should be available in most cases," and concludes that the default value of 20% "is likely to be used infrequently with the Exposure Decision Tree approach." However, rather than develop chemical-specific RSC values, USEPA (2000a) has chosen to rely on 20%, the most conservative allowable value, in its recent draft update of HHWQC (USEPA 2014a).

The California Office of Environmental Health Hazard Assessment (OEHHA) has concluded that the default use of an RSC of 20% is "unreasonably conservative for most chemicals" (Howd et al. 2004). For 22 of 57 chemicals listed by Howd et al. (2004), a RSC value greater than 20% was used in the calculation of California Public Health Goals for those chemicals in drinking water. Howd et al. (2004) also noted that "[a] default RSC of 0.2 is based on tradition, not data." Recently, the state of Florida developed specific RSC values for 21 of 35 noncarcinogenic compounds for which it derived HHWQC (FDEP 2014). Sixty-three percent of the RSC values used by Florida were greater than 0.2 (FDEP 2014).

The use of the 20% default value for RSC when a higher RSC value is warranted can result in as much as a 4-fold reduction in the HHWQC.

Body weight

The HHWQC methodology document (USEPA 2000a) recommends using a body weight (BW) of 70 kg. This weight was chosen in part because it is in the range of average weights for adults reported in several studies and in part because it is the default body weight used by USEPA's Integrated Risk Information System (IRIS) in dose extrapolation. However, in the updated edition of the Exposure Factors Handbook (USEPA 2011), USEPA recommends a mean BW of 80 kg for adults based on data from the National Health and Nutrition Examination Survey (NHANES) 1999 to 2006.

Because the toxicity parameters used in HHWQC derivation express exposure or risk as a function of body weight (e.g., mg of chemical per kg of body weight), the daily exposure that is likely to be without appreciable risk will be lower for an individual with a lower body weight than for an individual with a higher body weight. For this reason, the choice of 70 kg as the default body weight yields HHWQC that are approximately 12.5% lower than HHWQC calculated using the more representative current population mean of approximately 80 kg BW. In a recent draft proposed update of HHWQC, USEPA (2014a) acknowledged the increase in mean body weight and proposed to adopt 80 kg as the new default value for body weight.

Drinking water intake

The default drinking water intake (DI) used by USEPA in calculating HHWQC has been 2 L/d, which represents the

86th percentile for adults in a USEPA analysis of the 1994 to 1996 US Department of Agriculture (USDA) Continuing Survey of Food Intakes by Individuals (CSFII) data (USEPA 2000a). In the recently released draft update of HHWQC, USEPA (2014a) proposes increasing the default DI to 3 L/d, which is the 90th percentile for adults based on NHANES data from 2003 to 2006. The default water intake rate was selected in support of larger goals related to pollution prevention and maintenance of designated use (USEPA 2000a) and does not represent exposure that individuals are likely to receive from a regulated waterbody. A consumption rate of 2 or 3 L/d is based on estimates of direct and indirect water ingestion, primarily from municipal sources, groundwater, and bottled water, but not from untreated surface water. As USEPA (2000a) noted, it would be rare for anyone to use untreated surface water as a source of drinking water. Typically, direct consumption of untreated surface waters is limited to incidental ingestion during swimming, for which USEPA (2011) recommended upper percentile default intake rates of 120 mL/h for children and 71 mL/h for adults. Assuming the 95th percentile estimate for time spent swimming each month (181 min) (USEPA 2011) results in annual daily average incidental water consumption rates of 0.012 L/d (children) and 0.007 L/d (adults).

The effect on HHWQC of assuming 2 or 3 L/d varies according to the bioaccumulation factor (BAF) or bioconcentration factor (BCF) of the chemical. The HHWQC derivation equations consider exposures through both the direct consumption of a chemical in drinking water through the parameter "DI" and consumption of the chemical in fish tissues through the parameter "fish intake $\times$ BAF." Chemicals with high BAFs (or BCFs if BAFs are not available) will accumulate in fish tissues to a greater degree than chemicals with lower BAFs or BCFs. For chemicals with high BAFs or BCFs, the effect of drinking water intake on the ultimate HHWQC is minimal due to the much larger contribution of the "fish intake $\times$ BAF" factor in the equation. However, for substances with low BAFs or BCFs, the effect is much greater. For example, for methyl bromide, with a BCF of only 3.75 L/kg, the HHWQC calculated using a mean DI of 1 L/d (USEPA 2011) is 1.9 times greater than that calculated using 2 L/d and 2.8 times greater than when using 3 L/d.

Fish intake

The current USEPA Exposure Factors Handbook (USEPA 2011) contains summaries of a variety of surveys that have collected information on the consumption of fish, both by the general public and among specific subpopulations. The Handbook does not identify any single, specific fish consumption rate (FCR) that should be used for activities such as HHWQC derivation, but rather recommends that FCRs for the general population be based on a USEPA analysis of the 2003 to 2006 National Health and Nutrition Examination Survey (NHANES). USEPA (2011) provides a table containing per capita and "consumers only" mean and 95th percentile FCRs for "finfish," "shellfish," and "total finfish and shellfish" for all individuals, 9 different age classes, and females of reproductive age. Users are advised to select the FCR that best meets their needs from that data set.

However, USEPA (2011) also states that other relevant data on general population fish intake may be used if such data are more appropriate to the scenarios being assessed and notes that older data from the USEPA's analysis of data from the 1994 to 1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII) provide intake rates for freshwater or estuarine fish and shellfish, marine fish and shellfish, and total fish and shellfish that are not available from the NHANES analysis.

The default FCR used by USEPA in its derivation of HHWQC is 17.5 g/d, which represents an estimate of the 90th percentile per capita consumption rate of freshwater and estuarine fish for the general US adult population, based on 1994 to 1996 data from the CSFII (USEPA 2000a). In the 2014 proposed update to HHWQC, USEPA (2014a) has proposed to increase the default FCR to 22 g/d, which USEPA states represents the 90th percentile consumption of freshwater and estuarine fish for adults, based on 2003 to 2010 data from NHANES. FCR has received considerable attention during recent HHWQC revisions and reviews conducted by various states, with much discussion focused on how well the USEPA default value represents actual consumption of fish and shellfish and which fish and shellfish should be included in calculation of the FCR. Issues that have been raised include whether or not fish and shellfish harvested outside a state's jurisdiction should be included, whether or not marine species should be included, and how well the short-term food consumption surveys used by USEPA and some states as the basis for the default FCR represent long-term fish consumption rates (Polissar et al. 2012; FDEP 2014; USEPA 2014b).

The use of short-term data to represent long-term consumption of fish and shellfish. Both the CFSII and NHANES are short-term dietary intake surveys. Attempting to extrapolate long-term FCRs based on short recall period survey data presents a number of challenges. These include the potential misclassification of consumers as nonconsumers, the overestimation of upper percentile FCRs based on data collected as a snapshot in time, and the lack of consideration of variation over time (Ebert et al. 1994, WDOE 2013).

USEPA (2011) has acknowledged that short-term dietary records are problematic when attempting to estimate long-term rates of consumption, particularly for upper-bound FCR estimates. For example, in its review of NHANES 2003-2006 study data, USEPA (2011) stated that "the distribution of average daily intake rates generated using short-term data (e.g., 2-day) does not necessarily reflect the long-term distribution of average daily intake rates." Similarly, in a discussion of the limitations of a study of Michigan anglers (West et al. 1993), USEPA (2011) concluded that "because this survey only measured fish consumption over a short (1 wk) interval, the resulting distribution will not be indicative of the long-term fish consumption distribution, and the upper percentiles reported from the USEPA analysis will likely considerably overestimate the corresponding long-term percentiles." In addition, when discussing the methodology used by USDA in the CFSII, USEPA (1998) stated that "[t]he nonconsumption of finfish or shellfish by a majority of individuals, combined with consumption data from high-end consumers, resulted in a wide range of observed fish consumption. This range of fish consumption data would tend to produce distributions of fish consumption with larger variances than would be associated with a longer survey period, such as 30 days." The effect would be expected to be even larger for multiyear exposures and the lifetime consumption estimate that is implied using the currently recommended methodology for deriving HHWQC. As a result, upper-bound fish consumption estimates based on these data are biased high and overestimate actual upper-bound consumption rates for the total population of consumers.

Some researchers have developed methodologies to address the biases associated with using short-term data to estimate long-term consumption (Tran et al. 2004, 2013; Tooze et al. 2006). In support of the state of Washington's ongoing review and revision of their HHWQC, Polissar et al. (2012) derived FCRs based on the 2003 to 2006 NHANES data using 2 methodologies. The first used only the data as collected and standard survey estimation procedures. The second used the method developed by Tooze et al. (2006), commonly referred to as the National Cancer Institute (NCI) method, to provide more accurate estimates of long-term consumption for foods like fish that tend to be consumed on a more intermittent basis. USEPA (2014b) recently acknowledged the value of the NCI approach, stating that it is "the preferred method for estimating fish consumption rates." The state of Florida, in the most recent draft Technical Support Document (TSD) developed in support of its current HHWQC revision process, also adjusted the 2003 to 2006 NHANES FCR data using the NCI method (FDEP 2014). FCRs for consumers derived using the NCI method are approximately 3-fold lower than those based on unadjusted NHANES data and would yield HHWQC that could be as much as 3-fold greater, although the magnitude of the increase is a function of the BAF or BCF.

Source of fish consumed. USEPA (2000a), in the guidance for derivation of HHWQC that was issued in 2000, encourages states and authorized tribes to derive HHWQC using FCRs based on actual data if such data are available. This may be particularly important in the case of coastal states or in interior states with limited water resources, where national data may not accurately reflect typical consumption patterns. USEPA's first preference is the use of results from fish consumption surveys of local watersheds within the state or tribal jurisdiction to establish fish consumption rates that are representative of the defined populations being addressed for the particular waterbody (USEPA 2000a). However, USEPA has recently provided additional information on what sources should be considered in the determination of FCR via a "Frequently Asked Questions" (FAQ) document (USEPA 2013). According to the FAQ, "[b]ecause the overall goal of the criteria is to allow for a consumer to safely consume from local waters the amount of fish they would normally consume from all fresh and estuarine waters, the [fish consumption rate] does include fish and shellfish from local, commercial, aquaculture, interstate, and international sources." Thus, rather than a reflection of actual consumption of fish from waterbodies that are regulated by a state's HHWQC, USEPA (2013) recommended that the fish consumption rate represent the total consumption of freshwater and estuarine fish and shellfish regardless of location of harvest, or whether or not the source is aquaculture or harvest from the wild.

The consequence of this policy decision by USEPA is that the fish consumption rate used in the calculation of HHWQC may substantially overestimate consumption of fish from regulated freshwater and estuarine waters by the majority of the population. For example, according to the National Oceanic and Atmospheric Administration (NOAA) 2011 report on "Fisheries of the United States," 91% of the seafood consumed in the United States is imported (i.e., harvested or processed outside the United States or US territorial waters), although a small portion of that was harvested in US waters, exported overseas for processing, and then reimported (NOAA 2012). Approximately 93% of shrimp, which is by far the most frequently consumed seafood in the United States, is imported (NOAA 2012).

Eight of the top 10 types of seafood consumed in the United States are either marine species or the product of aquaculture, and thus are not harvested from regulated freshwater or estuarine waters (MBA 2011). Tilapia, catfish, and pangasius, which are the most commonly consumed freshwater fish, are the products of aquaculture and, for the most part, imported from outside the United States (MBA 2011).

Excluding marine fish and shellfish from the FCR. USEPA (2000a) recommends that the fish consumption rate used to develop the HHWQC be based only on consumption of freshwater or estuarine species, with exposures via consumption of marine species being accounted for through the RSC, although coastal states and authorized tribes that believe including marine species in the total FCR is more appropriate for protecting the population of concern may do so. The CFSII (source of the current USEPA default FCR) does differentiate between freshwater, estuarine, and marine species, but NHANES (recommended source of fish consumption data in the 2011 USEPA Exposure Factors Handbook) does not. Thus, if a FCR is selected based on NHANES data, consumption of marine species will unavoidably be included in the FCR. As an alternative, USEPA (2014b) recently obtained nonpublicly available 24 h recall files with raw data from NHANES from 2007 to 2008, which it used to apportion fish intake among marine, estuarine, and freshwater sources to inform the selection of a default freshwater plus estuarine FCR for its draft update of HHWQC.

To both base its HHWQC on the most recently available FCR data, and exclude consumption of marine species when appropriate, the state of Florida, as part of its ongoing HHWQC revision process, developed a 2-part approach for adjusting FCR data. As described above, the state first adjusted 2003 to 2006 NHANES FCR data using the NCI method to more accurately reflect long-term consumption patterns. Then the NCI-NHANES FCRs were further adjusted (reduced) by applying an adjustment factor of 0.377, which is based on a ratio derived from 1994 CFSII data on combined freshwater and estuarine consumption and total consumption (freshwater, estuarine, and marine) (FDEP 2014).

Fish tissue concentration

An implicit assumption in the derivation of HHWQC is that any given HHWQC corresponds to some specific fish tissue concentration. However, the amount of any particular substance to which consumers are exposed through the consumption of fish will be affected not only by the concentration of that substance in surface waters and the quantity of fish consumed, but also by the type of fish consumed and how that fish has been prepared.

Cooking loss. The derivation of HHWQC is based on the weight of raw fish consumed and the implicit assumption that there will be no reduction in chemical concentrations in fish tissues as a result of cooking and preparation processes. However, numerous studies have shown that cooking reduces the levels of some chemicals (Skea et al. 1979; Sherer and Price

1993; Zabik et al. 1995, 1996; Zabik and Zabik 1995, 1996). For example, Zabik et al. (1995) reported that cooking significantly reduced levels of the DDT complex, dieldrin, hexachlorobenzene, the chlordane complex, toxaphene, heptachlor epoxide, and total PCBs. Similarly, Sherer and Price (1993), in a review of published studies, reported that cooking processes such as baking, broiling, microwaving, poaching, and roasting removed 20% to 30% of the PCBs whereas frying removed more than 50%.

In its development of Fish Contaminant Goals (FCGs) and Advisory Tissue Levels, the State of California uses a cooking reduction factor to account for cooking losses for some chemicals (Cal/EPA 2008). Because the concentration of PCBs and some other organic chemicals in fish are generally reduced by at least 30%, depending on cooking method, the state included a cooking reduction factor of 0.7 in the FCG equation for organic compounds, which assumes 70% of the chemical remains after cooking (Cal/EPA 2008). USEPA also recommends that cooking loss be taken into account when setting fish advisories (USEPA 2000b). Although fish advisories are typically based on fish tissue levels rather than water concentrations, the same principle applies, because any HHWQC does translate to an equivalent fish tissue concentration for that substance.

By not incorporating a chemical-specific factor to adjust for cooking loss in HHWQC derivation, exposure associated with fish consumption may be overestimated for certain organic compounds, yielding lower HHWQC.

Lipid content of fish tissue. For nonionic chemicals, the lipid content of fish tissues is an important determinant of the degree to which those chemicals will accumulate in fish tissues. As part of outlining a process for developing national BAFs, USEPA (2003a) recommended national default lipid contents of 1.9%, 2.6%, and 3.0% for tropic level 2, 3, and 4 fish, respectively. These specific values were cited (USEPA 2003a) as being the consumption-weighted means for aquatic organisms commonly consumed throughout the United States. Florida recently examined this issue using state-specific data, and determined that the consumption weighted average lipid content for Florida consumers was 1.7%.

USEPA (2014b), in its recent HHWQC draft update, used BCFs based on the assumption that all fish consumed contain 3% lipid. This implies the assumption that 100% of fish consumed are from trophic level 4, based on the previous defaults recommended by USEPA (2003a). Based on the FDEP (2014) determination that the consumption weighted average lipid content for Florida consumers was 1.7%, use of a single BCF based on 3% lipids overstates bioconcentration in fish consumed by Florida residents, and thus overstates the risk associated with consuming fish caught in Florida (FDEP 2014). Similarly, the assumption of 3% lipid content likely overstates bioconcentration and risk for the general public, given that several of the most commonly consumed types of seafood in the United States (MBA 2011) are lower trophic level species (e.g., shrimp, tilapia, crab). For example, the most commonly consumed seafood in the United States is shrimp (MBA 2011), which has a lipid content of 1% to 2% (FDEP 2014).

Exposure duration

Exposure duration is an implicit element in the derivation of HHWQC for carcinogens and a value of 70 y, or an approximate lifetime, is assumed. Although average lifetimes may be approximated by 70 y, few people will drink and fish only one set of waters for an entire lifetime. Choosing to assume a 70 y exposure duration may be appropriate in cases where a chemical is ubiquitous in the environment (e.g., chemicals for which atmospheric deposition is the dominant mechanism for entry into surface waters) and it could reasonably be assumed that ingestion of drinking water and locally caught fish from all freshwater locations would lead to similar levels of exposure. There is little evidence, however, supporting the ubiquity of most substances for which HHWQC have been established.

However, many individuals move one or more times during their lifetimes and, as a result of those moves, may change their fishing locations and the sources of the fish they consume, thus changing their potential exposure profile. For example, a Pew Research Center study (Taylor et al. 2008) found that 63% of Americans have moved to a new community at least once in their lives and 43% of Americans have lived in 2 or more different states. In addition, it is likely that most anglers will not fish every year of their lives. Health issues and other demands, like work and family obligations, will likely result in no fishing activities or reduced fishing activities during certain periods of time that they live in a given area.

It is difficult to quantify the impacts of mobility and fishing habits on actual duration of exposure, especially because it seems reasonable to suspect that tribal, subsistence, and low income fishers (high level consumers) might be less mobile relative to the general population. However, the assumption of a 70 y exposure duration for all members of the population clearly adds conservatism to the derivation of HHWQC.

Surface water concentration

Implicit in the derivation of HHWQC is the assumption that both the water column and fish tissue concentrations exist at their maximum allowed for the entire implied 70 y exposure duration. In reality, water column concentrations vary over time and space. The assumption that water concentrations are always equal to the HHWQC and fish tissue concentrations are equal to those expected following continuous exposure to the HHWQC adds an additional layer of protectiveness because, as a practical matter, regulations governing water quality in the United States would not allow most regulated chemicals to persist in a water body at the HHQWC concentration for such an extended period. Exceptions to this may be chemicals whose primary sources are beyond the reach of water quality regulatory programs (e.g., airborne Hg, naturally-occurring As).

USEPA's Impaired Waters and Total Maximum Daily Load Program provides guidance to states concerning when waters are to be listed as impaired under the terms of the Clean Water Act. The USEPA guidance does not provide specific recommendations for identifying stream impairments due to exceedances of HHWQC, and state impaired stream listing methodologies often do not include specific provisions. In general, states seem to adopt 1 of 2 approaches: a specific limit on the number of exceedances of water quality limits for some fixed duration or the "10% Rule." Alabama Department of Environmental Management (2012), for example, considers listing a waterbody if "[t]here is more than one exceedance of a particular toxic pollutant criterion in [the] previous six years."

West Virginia Department of Environmental Protection (2012), on the other hand, applies the "10% Rule," stating that "if an ample data set exists and exceedances of…human health protection criteria occur more than 10 percent of the time, the water is considered to be impaired."

No matter which approach is adopted, average concentrations must be lower than the HHWQC to ensure that exceedances do not occur. This situation is acknowledged in the USEPA (2003b) guidance for listing impaired surface waters, which states that "[u]sing the '10% rule' to interpret data for comparison with chronic WQC will often be consistent with such WQC because it is unlikely to lead to the conclusion that water conditions are better than WQC when in fact, they are not." Based on the 10% rule, it would be more accurate to identify the HHWQC as the 90th percentile value in a distribution of water column concentrations existing over 70 y rather than a concentration to which living organisms are continuously exposed.

COMPOUNDED CONSERVATISM IN DERIVATION OF HHWQC

Most of the USEPA-recommended default values representing exposure parameters and implicit assumptions used in the derivation of HHWQC are selected from the upper percentiles of available data ranges (USEPA 2000a). The overall consequences of such choices have been acknowledged and addressed by regulatory agencies and individual researchers. For example, in its Cancer Risk Assessment Guidelines USEPA (2005) cautioned that combining multiple overly conservative assumptions is likely to lead to risk estimates that are above the 99th percentile of the distribution of potential risk and may be of limited use to decision makers. Similarly, Lichtenberg (2010) noted that the use of conservative default parameters introduces an upward bias into estimates of risk, and concluded that "the numbers generated by such procedures cannot really be thought of as estimates of risk, because they bear only a tenuous relationship to the probability that individuals will experience adverse health consequences or to the expected prevalence of adverse health consequences in the population."

A sense of what compounded conservatism means in the context of HHWQC derivation may be gained by estimating the proportion of the total population composed of individuals exposed at the levels represented by the default parameter values. Ten percent of the general population consumes the default 17.5 g/d or more of freshwater or estuarine fish (USEPA 2000a). Fourteen percent of the population consumes the default 2 L/d or more of water (USEPA 2000a). However, only 1.4% of the population is likely to consume at least 17.5 g/d of fish and drink at least 2 L/d of water.

This shows the effect of compounded conservatism for just 2 exposure assumptions. When other factors that affect the exposure assumptions are considered, such as that most of the fish consumed in the United States are imported and that it is unlikely that any individual will use untreated surface water as a regular source of drinking water, it is clear that HHWQC are based on exposures that are relevant for much less than 1% of the population, which is substantially more conservative than the goals (90th percentile, 10^{-6} risk level) recommended by USEPA.

Although the toxicity factors used in derivation of HHWQC have not been a focus of this article, they also contribute to the compounding of conservatism in HHWQC. Consider, for example, the UFs that are used by USEPA in the derivation of RfDs, which are in turn used in the calculation of HHWQC for substances with noncarcinogenic effects and substances such as chloroform, which has a nonlinear dose–response for carcinogenic effects. In RfD derivation, UFs are used to adjust the selected dose level from the underlying toxicological study to account for scientific uncertainties related to variations in sensitivity among humans (UF_H), extrapolation from animal studies to humans (UF_A), extrapolation from less than chronic (i.e., subchronic) no observed adverse effect levels (NOAELs) to chronic NOAELs (UF_S) or use of a lowest observed adverse effect level (LOAEL) rather than a NOAEL (UF_L) to define the RfD (USEPA 2000c). A default UF of 10 is typically used for each source of uncertainty noted above, although in some cases, a reduced UF of 3 is applied when available data or scientific understanding indicate that there is more certainty as a result of the availability of more data or a greater understanding of mode of action (USEPA 2000c). As noted by Gaylor and Kodell (2000), multiplying several uncertainty factors, each of which represents an upper bound estimate, results in an unnecessary compounding of conservatism, because it is unlikely that each uncertainty factor needs to be simultaneously at the maximum value. Similarly, Swartout et al. (1998) pointed out that the multiplication of conservative UFs acts to "repeat" conservative assumptions at each step of the process. For example, Swartout et al. (1998) concluded that default UFs of 100, 1000, and 3000, for application of 2, 3, and 4 UFs, respectively, could be replaced with UFs of 51, 234, and 1040 and still maintain a 95th percentile level.

USEPA (2000a) recommends the use of parameter values that are a combination of medians, means, and upper percentile estimates that target the high end of the general population to derive HHWQC. In actual practice, however, the selection of values representing explicit exposure parameters and the assumptions embodied by implicit parameters in the criteria derivation methodology represent upper-bound values in nearly all cases, resulting in HHWQC that greatly exceed the level of protectiveness identified by USEPA (2000a) as the basis for the HHWQC.

ALTERNATIVE APPROACHES

HHWQC that are more closely aligned with USEPA's stated protectiveness goals might be derived by selecting default parameter values from distributions that more accurately reflect current data or better represent long-term behavior, such as using NCI method-adjusted NHANES data on fish consumption. In the recently released draft update of HHWQC, USEPA (2014a) has adopted this approach. For example, the agency has proposed to increase the default value for BW to 80 kg and adjust fish consumption data to reduce bias due to the use of short-term consumption data as a surrogate for long-term fish consumption rates (USEPA 2014a).

Another alternative would be to replace some of the upper-end default values with mean and median values, and explicitly address some of the implicit parameters by selecting specific values for those parameters from the published scientific literature and regional studies. For some exposure parameters, sufficient data are available to provide complete distributions from which mean, median, or alternative percentile values may be selected for use. For example, the most recent Exposure Factors Handbook (USEPA 2011) contains complete data distributions, based on large national surveys, for drinking water intake. The primary obstacle to application of this approach is a lack of guidance on which upper-end percentile default exposure parameter values should be replaced with mean or median values, or accepted guidance upon which such choices should be based.

Another option would be to replace the current deterministic approach to HHWQC derivation with a probabilistic approach, such as that proposed by the state of Florida (FDEP 2014). In the Florida approach, distributions rather than point estimates were used for body weight, drinking water intake, and fish consumption rate (FDEP 2014). FDEP (2014) explained their preference for the probabilistic approach:

"Reliance on point values discards valuable information on variability within population. Furthermore, use of the deterministic approach has led to a focus on the wrong endpoints. The focus of criteria development should not be selection of a fish consumption rate or any other point value, but rather on setting criteria at the concentration of a pollutant in water that is not expected to pose a significant risk to human health over a lifetime. The probabilistic approach allows the focus to be shifted back to the true concern, specifically, the risk of exceeding the RfD or risk-specific dose (10^{-6}/cancer slope factor, RSD)."

Under Florida's probabilistic approach, body weight, drinking water intake, and fish consumption rate data are inserted into the equation as probability distributions based on variability in the target population (FDEP 2014). The analysis treats the exposure distributions as random variables and allows for an evaluation of risk to both the entire population and to higher risk subpopulations (FDEP 2014). This allows the risk assessor to specify the desired risk management endpoint and then demonstrate that the endpoint is met by the HHWQC. For example, for carcinogens, FDEP (2014) proposed HHWQC ensuring that average Floridians will be protected at greater than the 10^{-6} risk level, regular (weekly) consumers of Florida fish will protected at the 10^{-5} level, and that all Floridians, including subsistence fishers, will be protected at better than 10^{-4}. For noncarcinogens, FDEP (2014) calculated a Hazard Quotient (HQ) (total intake from fish and drinking water divided by the RfD, and then multiplied by body weight), then proposed HHWQC that achieve a HQ of 1.0 at the 90th percentile, which ensures that exposures to a large majority of the population will not exceed the RfD.

CONCLUSION

Despite USEPA (2000a) guidance to use "combinations of median values, mean values and percentile estimates that target the high end of the general population" when deriving HHWQC for the protection of public health, most states and tribes have calculated criteria using values from the upper ends of distributions for the exposure parameters. Also, several parameters, for which upper percentiles or maximums are employed, are implicit in the derivation methodology (e.g., assuming zero loss due to cooking) and contribute additional conservatism. Such conservative selections for these exposure parameters, combined with conservative toxicity parameters, can result in criteria that are substantially more protective than implied by USEPA's recommended health protection goals because of the compounding effect that occurs when multiple conservative factors are combined. This situation may be mitigated by thoughtful selection of exposure parameter values when using a deterministic approach, or by using a probabilistic approach based on data distributions for many of these parameters.

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